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Michael T. Milbocker

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09/10/2004

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|-----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/020,331 | MILBOCKER, MICHAEL T. | |
| | Examiner | Art Unit | |
| | Blessing M. Fubara | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 15, 16 and 31-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17-30 and 40-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>04/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of IDS, request for extension of time, amendment and remarks filed 04/21/04. Claims 31-39 were withdrawn from consideration because the claims are drawn to non-elected invention. Applicant in the current amendment withdraws claims 15 and 16 from consideration. Applicant adds new claims 40-48 but does not indicate if these new claims read on the elected invention. Applicant also indicates that 39 claims are pending. However, applicant has not cancelled any claims and the claims thus pending are 1-48 with claims 15, 16 and 31-39 withdrawn from consideration. It appears that applicant intended to cancel claims 15, 16 and 31-39 and if that is applicant's intention, applicant may cancel those claims in the next amendment if applicant so desires. New claims 40-48 are considered with claims 1-30.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 1-14, 17-30 and 40-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing for the following reasons:

It is not clear what the statement "wherein the polyol being terminated with at least one polyisocyanate in solution with at least (N-1)% of said solution."

The relationship of N in line 2 of claim 1 with N in (N-1) in line 3 of claim 1 is not clear.

Is the N the same as in both cases?

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Does the claim want to convey that the polyol is reacted with polyisocyanate/isocyanate in solution to form polyisocyanate terminated polyol that has N functional groups? What are the functional groups on these molecules? Isocyanate functional groups are assumed. Correction and clarification are respectfully requested.

Claim 1 is examined as biocompatible composition comprising a polyol that has N functional groups, wherein the polyol is terminated with at least one polyisocyanate and where 70% of the polyol is derived from ethylene oxide monomers. Tissue bonding adhesive is an intended use of the biocompatible polymer. How the polyol is formed or what the polyol is derived from is not critical to the polyol except the polyol is of a certain structure that is dependent on the source. In the generic claim, the polyol is treated as a polyol with no significance accorded to the source.

“Being terminated with at least one polyisocyanate in solution” is confusing in claims 1 and 17.

Claims 19 and 22 are not clear of what is meant by “less than 25% by molecular number of the total copolymer component.” Is the molecular number of the copolymer having fewer functional group 25% of the molecular number of the total copolymer component or is the copolymer having fewer functional group 25% by weight of the total copolymer?

What is water reactivity in claims 23 and 47?

In claims 23, 24 and 47, “both of said terminated polyols of functionality 1.5-8” is vague. Does the phrase imply that both polyisocyanate-terminated-polyol have 1.5-8 functional groups?

In claim 24, “said terminated polymers in solution with at least 1% of said solution comprising free polyisocyanate” is vague. Is ---are--- required between “in” and “solution” in

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claims 24 and 48 so that the phrase may read as follows: --- said terminated polymers are in solution with at least 1% of said solution comprising free polyisocyanate---

The sense of the use of "stoichiometric amounts" is not clear in claim 28.

3. Claims 44-45 recite the limitation "the surgical adhesive" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 40 does not provide antecedence for surgical adhesive since claim 40 does not recite surgical adhesive.

It is not clear how the polymerization steps fit in claims 44-45. Claim 44 is examined as a composition that consists essentially of at least one NCO-terminated branched polymer, derived from at least one organic polyisocyanate and at least 1% unreacted polyisocyanate.

Claim 45 is examined as a composition that consists essentially of at least one NCO-terminated branched polypropylene/poly-ethylene oxide copolymer, wherein copolymer A is at most 10% polypropylene oxide and copolymer B is between 10% and 30% polypropylene oxide, derived from an organic polyisocyanate and at least 1% unreacted polyisocyanate.

Claim 46 is examined as a composition that consists essentially of at least one NCO-terminated branched polypropylene/poly-ethylene oxide copolymer, wherein copolymer A is at most 10% polypropylene oxide and copolymer B is between 10% and 30% polypropylene oxide, derived from an organic polyisocyanate and at least 1% unreacted polyisocyanate.

Claims 44-46 depend from claim 40. How the polymer is derived is not accorded patentable weight. The claims may be amended to state ---consisting of--- in place of "derived from." If claims 45 and 46 are examined as stated above, then claim 46 is a duplicate of claim 45. If the polymerization steps are critical to the composition, the claims may be amended to

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read as proper product by process claims. In that case also, the claims will be examined as a product claims that contain the components in the process. See MPEP 2113 [R-1].

Claim 48 is not clear because it depends on itself. A claim cannot depend on it self.

Claim 48 is examined as being dependent on claims 47.

Correction is respectfully requested to make the claims definite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller et al. (US 5,624,972).

Muller discloses polymeric compositions comprising isocyanate-terminated polymers and a polyisocyanate composition (column 3, lines 8-16) and the composition comprises at least two polyisocyanate compositions, one is low in NCO polyisocyanate and the other is high NCO polyisocyanate (abstract). Toluene diisocyanate (claim 6) and isophorone diisocyanate (column 6, line 45) are examples of polyisocyanates. The functionality of the polyisocyanate terminated polyol is between 2 and 8 with an excess of isocyanate composition (column 3, lines 8-16). Additionally, Muller discloses that the composition comprises at least one other free polyisocyanate composition (See column 6, lines 38-62). Muller meets the limitations of claims 1-3 and 8.

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Claim Rejections - 35 USC § 103

6. Claims 4-7, 9-14, 17-30 and 40-48 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (US 5,624,972).

Applicant argues that no more than 30% propylene oxide and at least 70% ethylene oxide is required in the polymer and that Muller's composition cannot be used as a tissue adhesive.

7. Applicant's arguments filed 04/21/04 have been fully considered but they are not persuasive.

There is no demonstration that greater than 30% propylene oxide will not work in the composition. Secondly, the claim 1 does not specifically state that the polyol is 70% ethylene oxide. Future intended use is not critical in a composition claim and if the instant composition is applicable as a tissue adhesive, the composition of Muller should also be applicable as a tissue adhesive since Muller discloses polyol and polyisocyanate.

Specification

8. The disclosure is objected to because of the following informalities:

Page 5, first full paragraph has browser-executable codes such as ##STR6##, P.sub.1,

P.sub.2. Applicant is required to delete the browser-executable codes. See MPEP § 608.01.

Page 9, first full paragraph quotes '062 which should be '662 corresponding to 5,578,662 cited by applicant in line 1 of page 8. Same typographical misrepresentation of 5,578,662 appears on pages 10 (line 5) and 11 (line 1 of second paragraph).

---Not--- is misspelled "noot" on page 19, line 8 of first full paragraph.

Page 3, first full paragraph, line 1, "site" appears to be ---cite--

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Appropriate correction is required.

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification and in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

